24. (New) The method as defined in claim 14, further comprising the step of observing the second composition after contact with the gastric material to verify the presence or absence of urease in the gastric material.

25. (New) The method as defined in claim 18, further comprising the step of observing the composition after contact with the gastric material to verify the presence or absence of urease in the gastric material.

REMARKS

In the initial Office Action, all of the claims were indicated as being allowable over the prior art of record. The claims, however, were rejected for various informalities under 35 U.S.C. § 112. In response, various changes have been incorporated into the claims as suggested by the Examiner. Although amended, the scope of the claims remains unchanged.

In the Office Action, claims 11, 12 and 16 were objected to since, according to the Office Action, the term "pH adjuster" is indefinite and not commonly used in art. In response, Applicants submit that the term "pH adjuster" is described and defined in the specification in a manner sufficient to meet all of the requirements of 35 U.S.C. § 112. For instance, on page 3, the application states that a pH adjuster can be an acid or a buffering agent and can maintain the pH of a composition within preset limits. Further description of a pH adjuster is also included on page 12 of the application.

In the Office Action, claims 1, 14 and 18 were also objected to under 35 U.S.C. § 112 as being incomplete for omitting essential steps. Specifically, the Office Action states that the above claims omit a determination step. Reconsideration is respectfully requested.

For instance, claims 1, 14 and 18 are all directed to a method for detecting the presence of urease in a gastrointestinal system. Applicants submit that all of the essential steps of the method are included in the claims. For instance, each of the claims requires providing a sample of gastric material and contacting the gastric material with a composition that contains an indicator that indicates the presence of ammonia thereby indicating the presence of urease. Thus, the indicator determines whether or not urease is present in the gastric material. As such, it is believed that the claims recite all elements necessary to complete the defined method for detecting the presence of urease.

Applicants understand that the Information Disclosure Statement filed on November 13, 2002 was not considered since a legible copy of each reference was not provided. Enclosed as Appendix B is a copy of a returned postcard indicating that the U.S. Patent office did receive copies of each of the references included on the Information Disclosure Statement. Applicants intend to hand deliver all of the references to the Examiner in the future. In view of the enclosed postcard, it is believed that no fee should be required in considering the Information Disclosure Statement.

In summary, it is believed that the claims as currently amended are patentably distinct over the prior art and are in complete condition for allowance. Should any issues remain after consideration of this Amendment, however, then the Examiner is invited and encouraged to contact the undersigned at his convenience.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.

Timothy A. Cassidy
Registration No. 38,024

P. O. Box 1449
Greenville, SC 29602-1449
Phone: (864) 271-1592
Facsimile: (864) 233-7342

Date: 3/19/03

APPENDIX A

1. (Amended) A method for detecting the presence of urease in a gastrointestinal system comprising:

providing a sample of gastric material from a patient;

contacting said gastric material with a first powdered composition comprising urea, said urea being **[capable of being]** converted into ammonia when contacted with urease;

thereafter contacting said gastric material with a second composition comprising an indicator, **wherein, when ammonia is present**, said indicator **[being configured to indicate] indicates** the presence of ammonia thereby indicating the presence of urease in said gastric material.

2. (Amended) **The [A]** method as defined in claim 1, wherein said urea has a mean particle size of less than 0.1 mm.

3. (Amended) **The [A]** method as defined in claim 1, wherein said first **powdered** composition further comprises an anti-caking agent.

4. (Amended) **The [A]** method as defined in claim 1, wherein said second composition comprises a gel.

5. (Amended) **The [A]** method as defined in claim 1, wherein said second composition comprises agar in addition to said indicator.

6. (Amended) **The [A]** method as defined in claim 1, wherein said indicator comprises a pH indicator that changes color when the pH is increased.

7. (Amended) **The [A]** method as defined in claim 1, wherein said urea has a mean particle size of less than about 0.05 mm.

8. (Amended) **The [A]** method as defined in claim 1, wherein said first **powdered** composition and said second composition are positioned in the same container in a spaced apart relationship.

9. (Amended) **The [A]** method as defined in claim 1, wherein said second composition further comprises a bactericide or a bacteristat.

10. (Amended) **The [A]** method as defined in claim 1, wherein said indicator **[comprising] comprises** phenol red.

11. (Amended) **The [A]** method as defined in claim 1, wherein said second composition further comprises a pH adjuster.

12. (Amended) **The [A]** method as defined in claim 2, wherein said second composition further comprises agar and a pH adjuster.

13. (Amended) **The [A]** method as defined in claim 1, wherein said gastric material is contacted with said first **powdered** composition such that at least a portion of the urea is combined with the gastric material prior to being contacted with said second composition.

14. (Amended) A method for detecting the presence of urease in a gastrointestinal system comprising:

providing a sample of a gastric biopsy material from a patient;

contacting said gastric material with a first composition comprising urea, said urea being **[capable of being]** converted into ammonia when contacted with urease;

thereafter contacting said gastric biopsy material with a second composition comprising an indicator contained in a gel, **wherein, when ammonia is present**, said indicator **[being configured to change] changes** color for indicating the presence of urease in said gastric material.

15. (Amended) **The [A]** method as defined in claim 14, wherein said urea is present as a powder in said first composition.

16. (Amended) **The [A]** method as defined in claim 15, wherein said second composition further comprises agar and a pH adjuster, and wherein said indicator comprises phenol red.

17. (Amended) **The [A]** method as defined in claim 14, wherein said gastric material is contacted with said first composition such that at least a portion of the urea is combined with the gastric material prior to being contacted with said second composition.

18. (Amended) A method for detecting the presence of urease in a gastrointestinal system comprising:

providing a sample of gastric material from a patient;

contacting said gastric material with a composition comprising a powdered urea and a dry indicator, said urea being **[capable of being]** converted into ammonia

when contacted with urease and **wherein, when ammonia is produced**, said indicator **[being configured to indicate] indicates** the presence of ammonia thereby indicating the presence of urease in said gastric material.

19. (Amended) **The [A]** method as defined in claim 18, wherein said urea present within said composition has a mean particle size of less than about 0.1 mm.

20. (Amended) **The [A]** method as defined in claim 18, wherein said urea present within said composition has a mean particle size of less than about 0.05 mm.

21. (Amended) **The [A]** method as defined in claim 18, wherein said composition further comprises an anti-caking agent.

22. (Amended) **The [A]** method as defined in claim 18, wherein said indicator comprises a pH indicator that changes color when the pH is increased.